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Title: Implementing alcohol screening and brief interventions in primary health care: study protocol for a pilot cluster randomized controlled trial

Running head: Implementing alcohol screening and brief interventions

Article category – Study protocol

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KEY MESSAGES

- Alcohol brief interventions have been difficult to implement in practice
- Most implementation programmes have lacked a theoretical rational
- This trial will assess the efficacy of a new theory-driven approach

Abstract

Background. Alcohol is one of the most important risk factors contributing to the global burden of disease. Screening and brief interventions in primary care settings are effective in reducing alcohol consumption. However, implementation of such interventions in routine practice has been proven difficult. Most programmes in practice and research have lacked a theoretical rationale for how they would change practitioner behaviour.

Objective. To determine whether a theory-based behaviour change intervention delivered to primary care practices significantly increases delivery of alcohol screening.

Methods. We will conduct a two-arm, cluster-randomized controlled, parallel, open trial. Twelve primary care practices will be randomized to one of two groups: training and support; and waiting-list control. Family physicians, nurses and receptionists will be eligible to participate. The intervention will be a training and support programme. The intervention will be tailored to the barriers and facilitators for implementing alcohol screening and brief interventions following the principles of the Behaviour Change Wheel approach. The primary outcome will be the proportion of patients screened with the Alcohol Use Disorders Identification Test.

Conclusion. This study will test whether a theory-driven implementation programme increases alcohol screening rates in primary care. Results from this trial will provide a useful addition to existing evidence by informing implementation researchers what areas of behaviour change are critical to increasing alcohol screening rates.

Trial registration: clinicaltrials.gov NCT02968186

Keywords: Alcohol-Induced Disorders, Screening, Counselling, Patient Education, Primary Health Care, Behavior Control

Introduction

Background and rationale

Worldwide, alcohol is one of the most important risk factors for mortality (1). Amongst 15-64 year olds in the European Union, 14% of deaths in men and 8% in women are estimated to be alcohol-related.

Screening and brief interventions (SBI) in primary health care (PHC) settings are a range of "psychosocial interventions designed to help recipients recognise harmful patterns of substance use, and to motivate and support them to address that use" (2) ranging from five to 30 minutes, traditionally delivered face to face, and have long been advocated for preventing harm from alcohol use. Several randomized controlled trials and meta-analysis have found alcohol SBI to be effective and cost-effective or cost-saving (3-5). Notwithstanding recent debates concerning this effectiveness evidence (6), it is clear that alcohol increases the risk of and/or exacerbates many conditions that present in primary care (7), and that addressing alcohol in PHC settings still makes sense (8). PHC professionals are well-positioned to advise at-risk drinkers (9) and they support the principle of delivery of alcohol SBI (10). However, the majority of them do not routinely deliver such interventions (11, 12) and few at-risk drinkers visiting PHC currently receive alcohol-related advice or intervention (11, 13, 14). They are therefore denied the opportunity to understand the risks and make an informed decision about whether or not to cut down.

Whilst alcohol SBI may work in controlled trials, researchers continue to grapple with the challenge of how to achieve effective implementation in routine practice. Several factors have been identified hindering or facilitating implementation. Lack of time, lack of training, and lack of screening and counselling tools are among the most commonly cited barriers whereas involving all relevant staff, financial incentives, and the intensity of the intervention effort (i.e. the amount of training and/or support provided) are commonly reported facilitators (9, 14-16).

Training and related initiatives have met with only modest success in securing widespread implementation of alcohol SBI (17) with the possible exception of a large, highly funded, high profile programme in Scotland (18). Most programmes in practice and research have lacked a theoretical rationale for how they would change practitioner behaviour (19-21). For instance, in the recently published ODHIN multi-centre trial (22), three implementation interventions (training and support, financial reimbursement, and internet-based counselling) were provided separately and in combination to investigate their impact on the SBI

activity. Only training and support was proven to have a lasting, albeit small, effect on the SBI activity at 9 months of follow-up. However, the intervention components were not theory-driven which might have had a negative effect on the efficacy of the training and support package. Several other implementation programmes suffered from the same conceptual flaws (23-25). The intervention in our trial will differ from previous, more empirically-derived, strategies in that the intervention components (behaviour change techniques) were selected after a thorough analysis and mapping of the barriers and facilitators to implementation to their respective theoretical constructs. As such, the depth of the approach to intervention design will be greater in this study than has previously been the case.

By identifying theoretical concepts underpinning the barriers and facilitators to implementation, researchers can select intervention techniques that are predicted to lead to behaviour change (19, 26-28). One theory-driven intervention study is being tested by Abidi *et al*. (29) aiming to increase general practitioners' alcohol SBI delivery. In this study, general practitioners are invited to visit a website where they can access an e-learning module and receive tailored feedback and support. Our intervention will also differ substantially from the one reported by Abidi *et al*. (29) (see Supplementary Material S1 for a detailed description of the intervention). We will deliver a theory-based, face-to-face training and ongoing support intervention to all primary care staff. Involving all staff in the implementation efforts has been identified as an important facilitator for implementing alcohol SBI in PHC (30-33). Another example of an implementation facilitator we will use is to promote the exchange of positive experiences with peers (34, 35). Finally, by delivering face-to-face training, we will be able to use role-play for tackling several implementation barriers, such as lack of training and confidence in skills to deliver SBI.

The Context of the Trial

The trial will be conducted in the Dão Lafões Grouping of PHC in Portugal. Alcohol is the most commonly consumed addictive substance in Portugal, with 20% to 30% of over 18 year olds drinking at a hazardous level or higher (36). Patients at the Dão Lafões Grouping of PHC Centres have a mortality rate due to liver cirrhosis that is 48% higher than the national average (37). Under normal circumstances, professionals at these PHC centres would not receive any intervention focused on their practice relating to alcohol, over and above a normative expectation that they keep track of all national guidelines published by the National Health Directorate, which include guidelines on alcohol interventions (38).

Objective

The objective of this pilot trial is to determine whether a theory-based behaviour change intervention delivered to PHC practices significantly increases delivery of alcohol screening in those practices compared to delivery in practices assigned to a waiting list (treatment as usual) condition.

Trial design

We will conduct a cluster-randomized, waiting-list controlled, open trial, with two parallel groups, with a 1:1 allocation ratio. The unit of randomization will be the PHC practice. The study will pilot test the efficacy of a new programme tailored to the barriers and facilitators for implementing alcohol SBI.

Methods

This protocol was written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (39).

Study setting

The trial setting will be community-based PHC in Portugal. The Dão Lafões Grouping of PHC Centres comprises 26 PHC units, funded by the National Health Service. Each PHC unit is comprised of family physicians (FP), nurses, and receptionists. Each FP works preferably with the same nurse and receptionist, providing care to a list of patients (1600 to 1900 patients on average). Since 2005, PHC units in Portugal can be categorized into one of two models: the 'Personalized Health Care Units' (traditional PHC practices), in which professionals receive a fixed salary; and the 'Family Health Units', in which professionals work together to provide a more personal and flexible approach to the care of patients. Professionals at level-A Family Health Units still receive a fixed salary but if they achieve the quality indicators targets, they are upgraded to level-B units. Monthly income for professionals working in a level-B Family Health Unit depends on the base salary, patient list size, and pay for performance.

Eligibility criteria

All PHC units will be eligible to participate. PHC units will be excluded if they have less than five patient lists, or if they have a specific alcohol programme implemented in their practice but will be offered the programme after the end of the trial. All PHC professionals willing to participate will be enrolled.

Interventions

The intervention will be a package of training and support for PHC professionals. Prior to intervention design, we identified the barriers and facilitators to the implementation of alcohol SBI in PHC using three consecutive approaches. Firstly, we analysed a subset of qualitative data on barriers and facilitators identified in the BISTAIRS (Brief interventions in the treatment of alcohol use disorders in relevant settings) project. This was a European Union co-funded project in which two PHC units from the Dão Lafões Grouping of PHC Centres participated. Barriers and facilitators identified in this project (35) were mapped and included in the programme. Secondly, we analysed a subset of survey data on barriers and facilitators identified by the ODHIN (Optimizing delivery of health care interventions) project. This was also a European Union co-funded project in which a representative sample of 234 Portuguese FPs participated. Barriers and facilitators identified (40) by these FPs were also taken account of in the programme. With this approach, we aimed to identify the most important barriers and facilitators to alcohol SBI implementation that are both locally and nationally significant. Finally, the programme was informed by the results of a systematic review of the literature (41, 42). The barriers and facilitators identified using the three approaches above were collated and analysed with the Behaviour Change Wheel (BCW)/Theoretical Domains Framework (TDF). The BCW emerged recently as a comprehensive framework for designing interventions (27). The framework consists of three layers. At the core of the wheel (inner layer) there is a model of behaviour change designated as COM-B ('Capability', 'Opportunity', 'Motivation' and 'Behaviour'). The intermediate layer identifies nine intervention functions which are broader categories of means by which an intervention can change behaviour. The rim of the wheel comprises seven policy categories which represent the decisions authorities can use to support interventions. The COM-B model can be further expanded by the TDF (43). The TDF was derived from an

analysis of 33 theories of behaviour change and comprises 14 domains consisting of 84 component constructs of behaviour change. A Behaviour Change Technique (BCT) taxonomy has been developed to standardize the reporting of intervention content (26). BCTs are the smallest components of an intervention with the potential to change behaviour (44). The BCT taxonomy was used as the final step for designing the intervention. Finally, the selected behaviour change techniques were operationalized and integrated into a comprehensive implementation programme.

The implementation period will last for one year. Health professionals in the intervention arm will receive four training sessions (total of 30 hours) in the first 12 weeks of the implementation period. Training will be mainly delivered by FR, a local FP champion and certified trainer by the Portuguese Institute for Employment and Vocational Training, with experience in delivering training on alcohol SBI (see Supplementary Material S2–S5 for a detailed description of the training programme):

- Session 1 - participants will become familiar with the evidence concerning alcohol-related harm, and with the evidence for delivering alcohol SBI. Next, the notions of standard drink, risk continuum, daily drinking limits, and binge drinking will be presented. Participants will be told how to screen using the Alcohol Use Disorders Identification Test (AUDIT), and how to provide simple advice to patients with a positive screening. Barriers and facilitators for delivering alcohol SBI will be presented and discussed. Participants will be encouraged to adopt a working team model at their practices;
- Session 2 - participants will be asked to share experiences concerning implementation efforts in their practices. Next, participants will be introduced to the core concepts of brief intervention with a particular focus in the use of the OARS (Open-ended questions, Affirmations, Reflections, Summaries) skills. The transtheoretical model of behaviour change will be presented as a tool for determining patients' readiness to change;
- Session 3 - participants will be guided on how to tailor their actions to the stage of change the patient is at. This will be achieved through both group and individual exercises. Two specialists on alcohol dependence from a local recovery service will be talking about alcohol dependence and discussing clinical scenarios with the participants;
- Session 4 - participants will be asked to practice brief interventions.

Additional support will be continuously available to practices by means of a dedicated team that will help participants who have difficulties in implementing the project (see Supplementary Material S1 for a detailed description of the supporting actions). Posters specifically designed for this project will be made available to the PHC units which aim to help professionals to elicit alcohol issues during the consultations, and to help professionals to remember to conduct alcohol SBI. Patient leaflets were also specifically produced for this project, aiming to aid professionals in advising at-risk drinkers to cut down.

Participants in the control arm will be assigned to a waiting list. They will be provided with the Portuguese guideline for conducting alcohol SBI and the materials for the collection of research data, without demonstration. Participants in the waiting list will receive the program after a waiting period of one year.

Assessments

Doctors and nurses will be asked to fill in a questionnaire before randomization takes place. They will also be asked to fill in the same questionnaire at the end of the trial. The questionnaire aims to measure three distinct areas: attitudes to working with at-risk drinkers; barriers to implementing alcohol SBI and; knowledge about basic notions related to alcohol SBI.

Attitudes to working with at-risk drinkers: will be measured with the Short Alcohol and Alcohol Problems Perception Questionnaire (SAAPPQ), a validated scale based on factor analysis (36, 45). The SAAPPQ measures the level of agreement with ten statements on a seven-point Likert scale, from 1-strongly disagree to 7-strongly agree. Each pair of items measures a distinct dimension – Adequacy, Legitimacy, Motivation, Satisfaction and Self-Esteem;

Barriers for implementing alcohol SBI: will be assessed with an adapted version of an existing questionnaire (46). Participants will be asked to express their level of agreement with 33 statements on a seven-point Likert scale, from 1-strongly disagree to 7-strongly agree. Each statement can be mapped to a specific domain of the TDF. This will allow us to measure the impact of the implementation programme in each TDF domain;

Knowledge: will be evaluated by each participant's responses to four multiple choice questions. These questions will measure the theoretical knowledge to key concepts related to alcohol SBI, more

specifically the definition of standard drink, the definition of low risk drinking levels, and the AUDIT cut-off scores.

The questionnaire to be completed at the end of the trial will be the same, except for an additional section comprising seven questions. This section will be filled in only by participants in the intervention arm. Participants will be asked to rate the impact of the materials that were specifically produced for the study. Each statement will be measured on a seven-point Likert scale, from 1-strongly disagree to 7-strongly agree.

Primary outcome measure

Screening rate: professionals will be asked to screen patients who are 18 years old or older with at least one appointment during the 12-month implementation period excluding any duplicates. Patients will be screened based on the Portuguese guideline (38). At-risk drinkers are defined as patients scoring ≥8 on the AUDIT. Screening rates will be measured using paper tally sheets. Tally sheets will include the AUDIT, a table to indicate the action(s) taken for at-risk patients, participant's name, and a field to input patients' medical record number. The screening rate will be computed by dividing the number of completed screens by the total number of eligible patients, multiplied by 100.

Secondary outcome measures

Brief intervention rate: participants will be asked to deliver a brief intervention to at-risk drinkers. The brief intervention rate will be computed by dividing the number of brief interventions delivered by the total number of at-risk patients multiplied by 100.

Percentage of family physicians in the group with more positive attitudes: participants will be asked to fill in the SAAPPQ at baseline (T0), and at the end of the trial (T1). The answers will be used to determine in which group a FP is classified by applying the equation

$$P = 1/(1+\exp^{(-(-26.9732+0.9467*\text{Adequacy}+1.0552*\text{Self-Esteem}+1.0053*\text{Motivation}))})$$

that was previously validated (47). This classification model will be used to quantify, in each measurement period T, the percentage of FPs with more positive attitudes in the intervention and control groups.

Changes in barriers to implementing alcohol screening and brief intervention: will be ascertained with the answers to the barriers section of the questionnaire, and will be expressed by the average score in each domain of the TDF.

Level of knowledge: will be expressed by the percentage of correct answers on the third section of the questionnaire.

Usefulness of the materials: will be expressed by the average score on each of the relevant questions answered by the intervention group at the end of the trial.

Participant timeline, recruitment, allocation and blinding

The study flowchart is outlined in Figure 1. Firstly, a joint meeting will be scheduled with the coordinators of all 26 PHC units. The research team will present the protocol to the coordinators, and invite them to participate. During this meeting, 12 PHC units from those agreeing to participate will be randomly selected by ballot without replacement, stratified by type of organization. Secondly, individual meetings with each one of the 12 PHC units selected will be scheduled to present the project and invite all PHC professionals to participate. To take part in the trial, professionals will be required to sign a consent form. During this meeting, and prior to randomization into one of the trial arms, doctors and nurses will be asked to complete a questionnaire to measure knowledge, attitudes and barriers to implementing alcohol SBI. This approach will ensure that participants' answers will not be influenced by previously knowing whether they will receive the intervention or integrate a waiting-list. Finally, participants will be randomized at the PHC level by ballot without replacement, stratified by type of organization, into the intervention arm or the waiting list control arm.

Due to the nature of the study design, neither the research team nor the participants will be blinded to the allocation of the PHC units.

Sample size

The sample size was calculated on the basis of the primary hypothesis. Assuming a screening rate of 50% in the intervention arm, and 10% in the control group, power of 80%, alpha of 5%, intraclass correlation coefficient of 0.05, and a minimum of five patient lists per cluster, each arm will need to include five PHC units. The intervention rate estimation was based on the results of a meta-analysis (17). The control rate was based on the estimated annual screening rate at the Dão Lafões Grouping of PHC. To avoid loss of power due to loss to follow-up, six units will be included in each arm of the trial.

Data collection, management and monitoring

Data will be independently inputted into an Excel database by two members of the research team. Databases will be compared and checked for inconsistencies and errors. All data will be stored for a minimum period of 5 years in a lockable cabinet accessible only to the research team. No data monitoring committee will be established as no significant risks are anticipated to the participants in this study.

Statistical methods

Data will be described as frequency distributions, central tendency measures and dispersion measures as appropriate. Computations will be conducted as intention-to-treat analysis. Comparison of qualitative measurements will be performed with Pearson □ □ qui-square or McNemar test, as appropriate; comparison of quantitative variables will be conducted with Student's t-test for independent and related samples, as appropriate. Due to the cluster design of the trial, multilevel regression modelling will be conducted to assess the association of independent variables with the screening and brief intervention rates. A p-value <0.05 will be considered statistically significant.

Ethics and dissemination

The study protocol received approval from the Ethics Committee of the Faculty of Medicine of Lisbon (Ref. 359/19) and by the Ethics Committee of the Centre Regional Health Authority (Ref. 77/2016). Trial results will be presented to the participants in the study. The results will also be presented at scientific events and published in a scientific journal.

Discussion

For several decades now, researchers have tried to implement alcohol SBI programmes but evidence is still lacking regarding the optimal characteristics of training and support for alcohol screening and brief intervention delivery (48). Most studies reporting on training and support programmes present ill-defined descriptions, and considerable variation in terms of duration and intensity, contributing to the heterogeneity found in published trials (48). Most of these studies also lack a theoretical background underpinning the design of training and support.

To bridge this gap in the evidence base, this study aims to evaluate whether a theory-based implementation programme increases alcohol screening delivery by Portuguese primary health care practices. The implementation programme to be applied was tailored to the barriers and facilitators identified in the literature, underpinned by the BCW/TDF framework of behaviour change. Alcohol screening and brief intervention are underdelivered to the target population (13, 49, 50); we hypothesise that this programme will help to increase the delivery of screening (and related interventions) in primary health care. This in turn may help to ease the burden of disease attributable to alcohol. Results from this trial will provide a useful addition to existing evidence by informing implementation researchers about what areas of behaviour change are critical to increasing alcohol screening rates.

Conceptual flaws in the design of interventions might help to explain the modest increases in alcohol SBI activity achieved. Failure to implement alcohol SBI is leading researchers to think about scaling-up interventions to the system-level. One important quasi-experimental study is underway to test whether or not providing community and municipal support leads to higher alcohol SBI activity in PHC (51). This current line of thinking does not negate the value of exploring untested, less expensive approaches such as in this trial.

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Conflict of interest

None.

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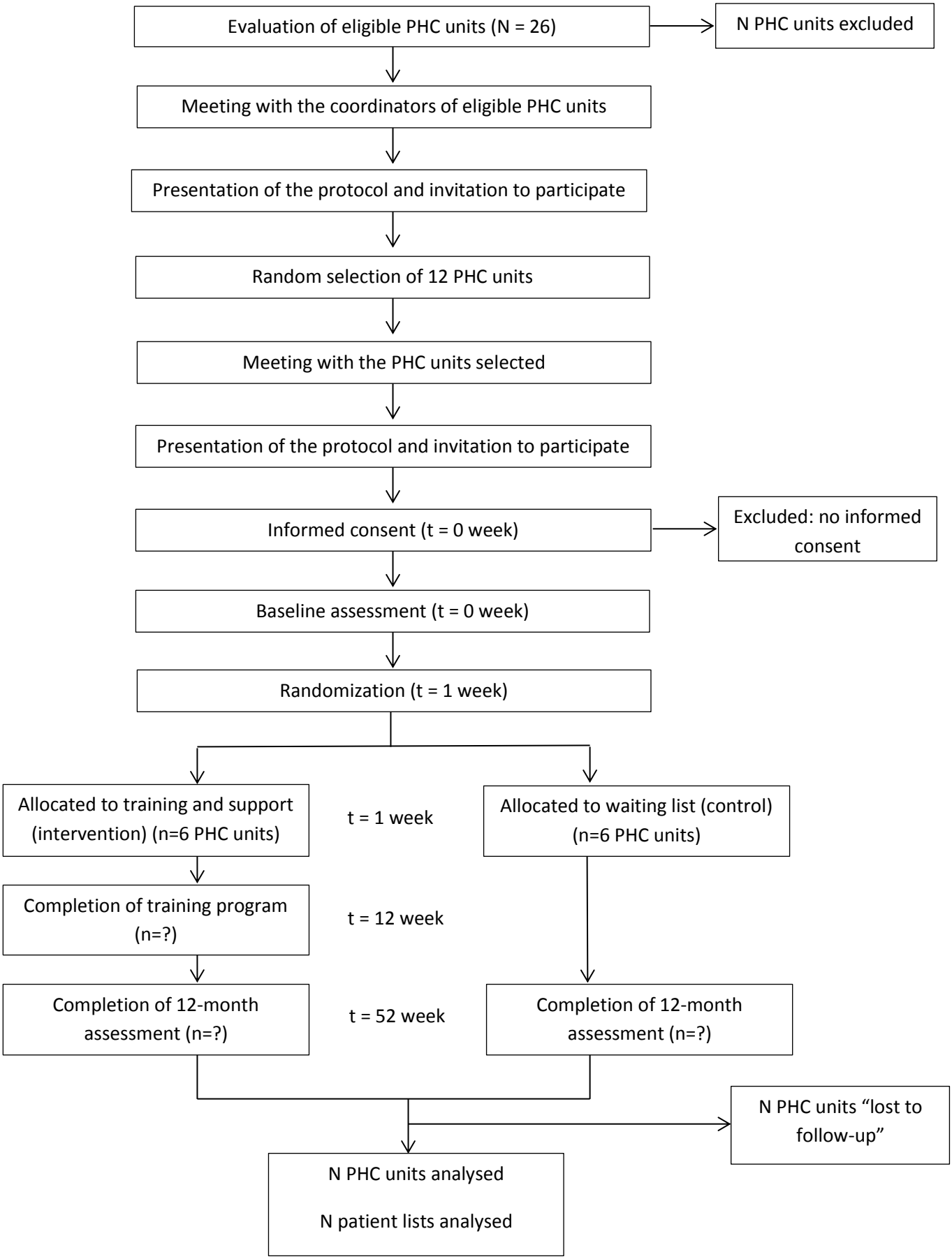
Figure 1


Evaluation of eligible PHC units (N = 26)
N PHC units excluded
Meeting with the coordinators of eligible PHC units
Presentation of the protocol and invitation to participate
Random selection of 12 PHC units
Meeting with the PHC units selected
Presentation of the protocol and invitation to participate
Informed consent (t = 0 week)
Excluded: no informed consent
Baseline assessment (t = 0 week)
Randomization (t = 1 week)
Allocated to training and support (intervention) (n=6 PHC units)
t = 1 week
Allocated to waiting list (control) (n=6 PHC units)
Completion of training program (n=?)
t = 12 week
Completion of 12-month assessment (n=?)
t = 52 week
Completion of 12-month assessment (n=?)
N PHC units "lost to follow-up"
N PHC units analysed
N patient lists analysed